

Remarks

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and the reasons that follow.

A detailed listing of all claims that are, or were, in the application, irrespective of whether the claims remain under examination in the application, is presented with appropriately defined status identifiers.

Claims 1, 17, 21 and 32 have been amended, and claims 5, 10, 19, 22 and 27 have been canceled (claims 9 and 26 were previously canceled). Upon entry of this Amendment, claims 1-4, 6-8, 11-18, 20, 21, 23-25 and 28-32 will remain pending in the application.

Support for the amendments to the following claims can be found at, e.g., the following places in the publication of the present application, US 2005/0112171:

- Claims 1 and 17 – paragraphs [0012] and [0031] to [0033]; and
- Claim 32 – claim 15 as originally filed.

The amendments to claim 21 merely correct obvious errors in the preamble of the claim.

Because the foregoing amendments do not introduce new matter, entry thereof by the PTO is respectfully requested.

Claim rejections under 35 U.S.C. § 102

On page 2 of the Action, the PTO rejects as allegedly anticipated claims 1-8, 10, 11, 15-25, 27, 28 and 32 over US 2004/0181271 to DeSimone *et al.* (“DeSimone”) under 35 USC § 102(e), claims 1-8, 10-25 and 27-32 over EP 0970711 to Hossainy *et al.* (“Hossainy 1”) under § 102(b), and claims 1-4, 11, 16-21, 28 and 32 over US 2001/0014717 to Hossainy *et al.* (“Hossainy 2”) under § 102(b), all for the same reasons given in the Office Action dated March 20, 2007.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v.*

Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP § 2131. An “inherent characteristic [must] necessarily flow[] from the teachings of the applied prior art.” *Ex parte Levy*, 17 USPQ 2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (original emphasis). “Inherency ... may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 1991) (quoting *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981)) (original emphasis).

Applicants rely on all the arguments made in the previous reply filed on June 18, 2007. In addition, Applicants make the following arguments.

1. Rejection over DeSimone

Applicants respectfully submit that DeSimone cannot anticipate any of the pending claims because DeSimone does not expressly or inherently describe each and every feature of any of these claims. For example, DeSimone does not expressly or inherently describe (1) a first bioerodable polymer having a glass transition temperature (T_g) below about -50°C and (2) a bioerodable polymeric additive having a degree of crystallinity greater than that of the first polymer, which are features recited directly or indirectly in each of the pending claims.

Relating to point (1), the PTO asserts, “DeSimone teaches that exemplary polymeric materials have a glass transition temperature between about 60°C to about -60°C ” (3/20/07 Action, page 4). Applicants respectfully point out that DeSimone actually teaches a T_g range between about 60°C and 65°C : “An exemplary polymeric material for intraluminal prostheses according to embodiments of the present invention may have a melting temperature between about 173°C - 178°C and a glass transition temperature of between about 60°C - 65°C ” (paragraph [0043]). Thus, DeSimone does not expressly describe a first bioerodable polymer having a T_g below about -50°C . DeSimone further states in vague terms that “[p]olymeric materials having various other melting temperatures and glass transition temperatures can be used, without limitation” (*id.*). A first bioerodable polymer having a T_g below about -50°C

cannot be said to *necessarily* flow from such vague language. The *mere possibility* of selecting a first bioerodable polymer having a T_g below about $-50\text{ }^{\circ}\text{C}$ from such vague language does not constitute inherent description of the claimed T_g feature.

Regarding point (2), DeSimone does not expressly or inherently describe a bioerodable polymeric additive having a degree of crystallinity greater than that of the first polymer. Nowhere in DeSimone does the reference teach or suggest this claimed crystallinity feature. In the present Action, the PTO makes an inherency argument based on crystallinity values for exemplary samples of poly(3-hydroxybutyrate) (3-PHB) and poly(caprolactone) (PCL) disclosed in the instant application. The PTO asserts that because DeSimone teaches a blend of PCL and PHB and because the instant application states that “the crystallinity of 3-PHB is about 80% while that of PCL is about 57%” (paragraph [0035]), “the [crystallinity] limitation is inherently met” (present Action, page 4). Since none of the pending claims presently recite 3-PHB as a polymeric additive, this inherency argument cannot be used to meet the claimed crystallinity feature. The PTO has provided no other evidence to support its assertion that the claimed crystallinity feature necessarily flows from the teachings of DeSimone. As Applicants noted in their 6/18/07 reply, “degree of crystallinity ... can be different for a [particular] polymer and depend upon the conditions under which the polymer is made and processed” (page 8).

Because DeSimone does not expressly or inherently describe each and every feature of any of the pending claims, DeSimone cannot anticipate any of these claims. Accordingly, Applicants respectfully request withdrawal of the anticipation rejection over DeSimone.

2. Rejection over Hossainy 1

Applicants respectfully submit that Hossainy 1 (EP 0970711) cannot anticipate any of the pending claims because Hossainy 1 does not expressly or inherently describe each and every feature of any of these claims. For example, Hossainy 1 does not expressly or inherently describe a bioerodable polymeric additive having (1) a degree of crystallinity greater than that of a first

bioerodable polymer and (2) a T_g of about -50°C or greater, which are features recited directly or indirectly in each of the pending claims.

Hossainy 1 does not teach or suggest at all the claimed crystallinity feature (1). As explained above, the PTO's inherency argument based on the crystallinity values for exemplary samples of 3-PHB and PCL disclosed in the instant application does not apply because none of the pending claims presently recite 3-PHB as a polymeric additive. The PTO has provided no other evidence to support its assertion that the claimed crystallinity feature necessarily flows from the teachings of Hossainy 1. Thus, Hossainy 1 does not expressly or inherently describe a bioerodable polymeric additive having a degree of crystallinity greater than that of a first bioerodable polymer.

In addition, nowhere in Hossainy 1 does the reference teach or suggest a bioerodable polymeric additive having a T_g of about -50°C or greater. In fact, the PTO has admitted that "Hossainy does not specifically mention the glass transition temperatures of the polymers" disclosed therein (3/20/07 Action, page 7). Further, the PTO has offered no evidence that the claimed T_g feature (2) for any of the presently recited polymeric additives necessarily flows from the teachings of Hossainy 1. It is well known in the art that the T_g of a particular homopolymer or copolymer depends on the manner in which it is made and processed. Therefore, Hossainy 1 does not expressly or inherently describe a bioerodable polymeric additive having a T_g of about -50°C or greater.

Because Hossainy 1 does not expressly or inherently describe each and every feature of any of the pending claims, Hossainy 1 cannot anticipate any of these claims. Accordingly, Applicants respectfully request withdrawal of the anticipation rejection over Hossainy 1.

3. Rejection over Hossainy 2

Applicants respectfully submit that Hossainy 2 (US 2001/0014717) cannot anticipate any of the pending claims because Hossainy 2 does not expressly or inherently describe each and

every feature of any of these claims. For example, Hossainy 2 does not expressly or inherently describe any of the presently recited bioerodable polymeric additives having (1) a degree of crystallinity greater than that of any of the presently recited first bioerodable polymers and (2) a T_g of about -50°C or greater, which are features recited directly or indirectly in each of the pending claims.

Hossainy 2 does not teach or suggest at all the claimed crystallinity feature (1). As explained above, the PTO's inherency argument based on the crystallinity values for exemplary samples of 3-PHB and PCL disclosed in the instant application does not apply because none of the pending claims presently recite 3-PHB as a polymeric additive. The PTO has provided no other evidence to support its assertion that the claimed crystallinity feature necessarily flows from the teachings of Hossainy 2. Therefore, Hossainy 2 does not expressly or inherently describe any of the presently recited bioerodable polymeric additives having a degree of crystallinity greater than that of any of the presently recited first bioerodable polymers.

Moreover, Hossainy 2 does not teach or suggest any of the presently recited bioerodable polymeric additives having a T_g of about -50°C or greater. Hossainy 2 does not describe the T_g of any of the polymers presently recited as polymeric additives. Further, the PTO has provided no evidence that the claimed T_g feature (2) for any of the presently recited polymeric additives necessarily flows from the teachings of Hossainy 2. Thus, Hossainy 2 does not expressly or inherently describe any of the presently recited bioerodable polymeric additives having a T_g of about -50°C or greater.

Because Hossainy 2 does not expressly or inherently describe each and every feature of any of the pending claims, Hossainy 2 cannot anticipate any of these claims. Accordingly, Applicants respectfully request withdrawal of the anticipation rejection over Hossainy 2.

4. The PTO's inherency argument regarding crystallinity

In the present Action, the PTO makes the following inherency argument regarding the degree of crystallinity of a polymer. According to the PTO, because (1) the cited references teach blends containing the presently claimed polymers, (2) the references "recite or inherently teach the same T_g as claimed by applicants," and (3) the T_g of a polymer is "inherently linked to its [*sic*] crystalline structure" (citing Odian, Principles of Polymerization), "the polymers [disclosed in the references] will inherently have the same degree of crystallization as applicants [*sic*] claimed polymer blend" (present Action, pages 3-4).

Contrary to the PTO's suggestion, Odian does not teach that the T_g of a polymer necessarily directly correlates with its degree of crystallinity. In fact, it is recognized in the art that the T_g of a polymer does not necessarily directly correlate with its degree of crystallinity. The PTO also makes the inherency argument based on crystallinity values for exemplary samples of 3-PHB and PCL disclosed in the instant application (present Action, page 4). Because none of the pending claims presently recite 3-PHB as a polymeric additive, this inherency argument cannot be used to satisfy the requirement that a bioerodable polymeric additive have a degree of crystallinity greater than that of a first bioerodable polymer. Again, it is well known in the art that the degree of crystallinity of a homopolymer or a copolymer and, to a lesser extent, its T_g depend on the manner in which the homopolymer or copolymer is made and processed. In other words, the same kind of homopolymer or copolymer made by two different manufacturers using different processes and conditions can exhibit significant differences in their degree of crystallinity and, to a lesser extent, in their T_g .

Claim rejection under 35 U.S.C. § 103

On page 3 of the present Action, claims 1-8, 10-25 and 27-32 are rejected under 35 USC § 103(a) as allegedly being obvious over Hossainy 1 (EP 0970711) in view of DeSimone (*supra*) and/or in view of Hossainy 2 (US 2001/0014717) for the reasons give in the 3/20/07 Action.

To establish a *prima facie* case of obviousness, a combination of prior art references must teach or suggest to an ordinary artisan each and every feature of a claimed invention. MPEP § 2143.03.

Applicants respectfully submit that the combination of Hossainy 1, Hossainy 2 and DeSimone cannot render obvious any of the pending claims because the combination does not teach or suggest to an ordinary artisan each and every feature of any of these claims. For example, the cited combination does not teach or suggest any of the presently recited bioerodable polymeric additives having a degree of crystallinity greater than that of any of the presently recited first bioerodable polymers, which is recited directly or indirectly in each of the pending claims.

Nowhere in Hossainy 1, Hossainy 2 and DeSimone do any of these references teach or suggest the claimed crystallinity feature. The PTO has essentially acknowledged this fact by making the aforementioned inherency argument in the present Action. As explained above, the inherency argument cannot cure the cited combination's failure to teach or suggest any of the presently recited bioerodable polymeric additives having a degree of crystallinity greater than that of any of the presently recited first bioerodable polymers.

Because the combination of Hossainy 1, Hossainy 2 and DeSimone does not teach or suggest to an ordinary artisan each and every feature of any of the pending claims, the combination cannot render any of these claims obvious. Accordingly, Applicants respectfully request withdrawal of the obviousness rejection.

Conclusion


The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The PTO is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 07-1850. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 07-1850. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorize payment of any such extensions fees to Deposit Account No. 07-1850.

Respectfully submitted,

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By  _____

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